UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In Re Pharmaceutical Industry Average Wholesale Price Litigation	
This Document Relates To: GOVERNMENT EMPLOYEES HOSPITAL ASSOCIATION, individually and on behalf of all others similarly situated, Plaintiff v. SERONO INTERNATIONAL, S.A., SERONO LABORATORIES, INC., SERONO, INC., RJL SYSTEMS, INC., AND RUDOLPH J. LIEDTKE, Defendants.	MDL No. 1456 C.A. No. 05-cv-11935 (PBS)

FIRST AMENDED CLASS ACTION COMPLAINT AGAINST SERONO INTERNATIONAL, S.A., SERONO LABORATORIES, INC., SERONO, INC., RJL SYSTEMS, INC., AND RUDOLPH J. LIEDTKE

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I. NATURE OF THE ACTION

1. This is a proposed national class action brought on behalf of consumers and third-party payors (self-insured employers, Taft-Hartley funds, non-profit and for-profit heath insurers, all of whom bear the ultimate risk for prescription drug expense) against Serono International, S.A., Serono, Inc., Serono Laboratories, Inc. (collectively "Serono"), RJL System, Inc. ("RJL"), and Rudoph J. Liedtke ("Liedtke") seeking damages and other monetary relief by reason of the Defendants' deceptive and illegal marketing, sales, and promotional activities for the prescription drug Serostim.

2. In 1996, Serono obtained accelerated approval from the U.S. Food and Drug Administration ("FDA") for Serostim for the sole purpose of treating AIDS wasting. At the time, AIDS wasting was the leading cause of death among AIDS patients. But just as Serono was bringing Serostim to market, other drug companies were bringing to market a new class of drugs known as protease inhibitors that dramatically improved treatment of AIDS. These drugs, when used in various combinations commonly known as an "AIDS cocktail," dramatically curtailed the replication of the HIV virus in HIV infected individuals. As a result of the discovery of this new treatment, the prevalence of HIV conversion to AIDS and associated conditions, including AIDS wasting, diminished and the cases in which Serostim treatment was medically necessary radically declined.

3. Faced with faltering demand for a drug that had become marginalized by new and superior therapies, Serono embarked on a campaign of criminal deceit, manipulation, kickbacks and fraud to prop up the flagging market for Serostim.

4. Serono did not accomplish these deceptions on its own. Not only did Serono itself engage in acts of deceit, but it also contracted with medical device marketing firm RJL and its principal Liedtke to provide unapproved and unproven medical devices and

software, and to develop fraudulent and misleading tests, that would fabricate data to support prescription of Serostim where no medical necessity existed. It also contracted with consultants to communicate its fraudulent representations to physicians, payors, and the public. Serono also paid inducements to physicians, including lavish all-expense paid trips to Cannes, France, in exchange for agreements by those physicians to prescribe Serostim, and paid pharmacies to provide lists of physicians who were likely to prescribe Serostim and for other unlawful purposes. Thus, Serono associated itself with discrete, identifiable medical device makers, consultants, and others unknown to effectuate its deceptive and illegal marketing and promotional campaign to urge the prescription of Serostim based on unapproved diagnostic procedures in circumstances in which no proven medical necessity for the treatment existed.

5. From September 1996 through at least January 2002, Serono and RJL engaged in illegal conduct whose sole purpose was unlawfully to promote, market and sell Serostim in circumstances where the prescription of Serostim was not supported by proof of medical necessity. These schemes included:

6. *Medical Device Activities.* Promoting the use of unapproved, adulterated and unproven medical devices and computer software marketed by RJL and Liedtke to physicians which purported to calculate body cell mass wasting to fraudulently create a medical basis for prescription of Serostim; distributing these medical devices and computer software to physicians for the sole purpose of increasing the demand for Serostim; and training, authorizing and encouraging sales representatives to administer the purported body cell mass wasting tests to AIDS victims to fraudulently promote the sale of Serostim.

7. *Physician Kickback Activities*. Paying illegal inducements and kickbacks to physicians to induce them to prescribe Serostim. In particular, from March 1999 through December 1999, in an attempt to reverse the severe shortfall in sales of Serostim, offering physicians in exchange for writing up to 30 new prescriptions of Serostim a lavish all-expenses paid trip to a medical conference in Cannes, France. The sales strategy was part of a Serono marketing campaign referred to as the "$6m-6 Day Plan." Because each prescription encompassed a 12-week course of therapy that cost $21,000, the value of 30 prescriptions to be written by each doctor was $630,000. The Serono marketing department announced within the company that 10 physicians were "U.S. Invitees" to the Cannes conference with all expenses paid for them and their guest to attend. The 30 prescriptions each doctor was expected to write meant a total value of approximately $6.3 million in sales. Illegal inducements also included payment of stipends and honoraria for fictitious speaking engagements and facilitating billing by physicians to third-party payors for fraudulent body cell mass wasting tests that the physicians themselves did not perform.

8. *Over Prescribing Activities.* Fraudulently encouraging physicians to prescribe dosages of Serostim that the patients did not need or could not consume.

9. *Off-label Marketing Activities.* Marketing Serostim to physicians for the treatment of lipodystrophy, a separate condition involving weight gain in the mid-section and weight loss in the extremities, different from AIDS wasting, for which Serostim was not approved by the FDA.

10. Through these activities and others, Serono knowingly caused consumers and third-party payors to pay for Serostim treatments that were not proven to be medically necessary or were not provided at all.

11. On October 17, 2005 the United States Attorney for the District of Massachusetts Michael J. Sullivan announced that after a four-year investigation, Serono had would plead guilty to federal criminal and would pay civil restitution to settle civil charges for engaging in widespread fraudulent drug promotion and pervasive false and misleading marketing activities that resulted in false and fraudulent claims being submitted to federal and state third-party payor Medicaid. The settlement included the following elements:

12. *Guilty Plea to Criminal Conspiracy*. Serono Laboratories, Inc. would plead guilty to two counts of criminal conspiracy, to promote the use of adulterated medical devices with intent to defraud, and to offer and pay illegal remuneration. Serono Laboratories, Inc. would pay a criminal fine in the amount of $136.9 million. As a result of the criminal conviction, Serono Laboratories, Inc. also would be excluded from participating in any federal health care programs for a period of at least five years.

13. *Corporate Integrity Agreement.* Serono, Inc. and all other U.S. subsidiaries of Serono, S.A. would be subject to a stringent Corporate Integrity Agreement for five years.

14. *Restitution to the United States.* Serono would pay $305 million, plus interest, to the United States in civil damages for losses suffered by the federal portion of the Medicaid program and other federal health care programs as a result of fraudulent drug promotion and marketing misconduct attributed for purposes of the plea bargain and settlement to Serono Laboratories, Inc.

15. *Restitution to the States*. Serono would pay a total of $262 million, plus interest, to settle its civil liabilities to the 50 states and the District of Columbia for losses suffered by the state Medicaid programs.

16. In all, Serono was required to pay $704 million to state and federal officials in response to criminal and civil charges resulting from its illegal promotion of Serostim.

17. In April 2005, RJL and its President, Rudolph J. Liedtke, pleaded guilty to their roles in the conspiracy and are waiting sentencing.

18. In addition, on December 21, 2004, Adam Stupak, a Serono sales director, pleaded guilty to three counts of offering to pay illegal remuneration by offering doctors free trips to Cannes, France if they committed to write 30 prescriptions for Serostim in one week.

19. In addition, on April 15, 2005, four former executives of Serono were indicted on charges of offering bribes to doctors to prescribe Serostim. The indictments included charges of criminal conspiracy. The four people named in the indictment were John Bruens, marketing vice president; Mary Stewart, vice president of sales; Melissa Vaughn, regional sales director; and Marc Sirockman, regional sales director.

20. In announcing the criminal pleas and civil settlement, United States Attorney Sullivan stated that *nearly 85 percent of prescriptions written for Serostim were not medically necessary*. He also stated that the medical testing procedure concocted by Serono, RJL and Liedtke was "almost voodoolike," and that he suspected that some of the patients may also have suffered side effects as a result of taking the AIDS drug.

21. Serono's unlawful marketing and kickback activities resulted not only in fraud on the federal and state governments, but also in unnecessary payments by consumers and third-party payors. In addition, as stated by the Unites States Attorney for the District of Massachusetts, these activities may also have resulted in personal injury to AIDS victims

treated with Serostim. This First Amended Class Action Complaint seeks to address the economic harm suffered by consumers and third-party payors.

22. Count I alleges a violation of the Racketeering Influence and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961(c). Serono associated itself with a discrete and identifiable medical device marketing firm and its principal (hereinafter the "Serostim Medical Device Enterprise"), in order to form a RICO association-in-fact. Through the use of this enterprise, Serono engaged in a pattern of racketeering activity including promoting, distributing, and using adulterated, unapproved, and unproven medical devices and software throughout the country, and at least multiple episodes of mail fraud and wire fraud, for the purpose of conducting fraudulent body cell mass wasting tests in order to support the medically unnecessary prescription and sale of Serostim. Consumers and third-party payors were injured in their property by reason of these violations by, among other things, having to pay hundreds of million of dollars for Serostim by reason of the unlawful conduct. Plaintiffs seek certification of a nationwide class, and treble damages on behalf of that class.

23. Count II also alleges a violation of the Racketeering Influence and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961(c). Serono associated itself with discrete and identifiable physicians (hereinafter the "Serostim Physician Kickback Enterprise") in order to form a RICO association-in-fact. Through the use of this enterprise Serono engaged in a pattern of racketeering activity including offering and paying illegal remuneration and at least multiple episodes of wire fraud, for the purpose of conducting fraudulent body cell mass wasting tests in order to support the medically unnecessary prescription and sale of Serostim. Consumers and third-party payors were injured in their property by reason of these violations by, among other things, having unnecessarily to pay millions of dollars for Serostim by reason

of the unlawful conduct. Plaintiffs seek certification of a nationwide class, and treble damages on behalf of that class.

24. Count III alleges a conspiracy in violation of RICO under 18 U.S.C. § 1962(d). Serono and its co-conspirators engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, and by reason of this conduct consumers and third-party payors were injured in their property. Plaintiffs seek certification of a nationwide class, and treble damages on behalf of that class.

25. Count IV alleges a violation of state consumer protection law. As a direct result of Serono's deceptive, unfair, unconscionable, and fraudulent conduct, consumers and third-party payors were injured and suffered loss within the meaning of applicable and consumer protection statutes. Plaintiff seeks certification of a nationwide class or groups of classes and applicable damages on behalf of that class or classes.

26. Count V alleges common law fraud.

27. Count VI seeks relief in the nature of unjust enrichment. As a result of the intended and expected result of the conscious deceitful and illegal acts engaged in by Serono, Serono profited and benefited at the expense of the consumers and third-party payors in the United States.

28. Finally, pursuant to Fed. R. Civ. P. 38, the First Amended Class Action Complaint seeks a jury trial on all issues so triable.

II. PARTIES

29. Plaintiff Government Employees Hospital Association ("GEHA") is the third-largest national health insurance plan serving federal employees and retirees, as well as their families. GEHA has over 232,000 health plan members and provides health insurance to over 425,000 people across the United States and around the world. GEHA is a self-insured

and not-for-profit association. GEHA has paid for prescriptions of pharmaceutical products manufactured and marketed by Serono. GEHA is incorporated in the state of Missouri and its corporate offices are located at 310 N.E. Mulberry, Lee's Summit, Missouri 64056.

30. Defendant Serono International, S.A. is a Swiss global biotechnology company with over 4,500 employees, and worldwide revenues in 2001 of $1.38 billion. Serono International, S.A.'s registered office is located at Centre Industrial in 1267 Coinsins/VD, and its executive offices are located at 15bis, chernin des Mines, Case Postale 54, CH-1211 Geneva 20, Switzerland.

31. Serono Laboratories, Inc. is a U.S. subsidiary of Serono International, S.A., organized under the laws of Massachusetts and both located and headquartered at One Technology Place, Rockland, Massachusetts, 02370.

32. Defendant Serono, Inc. is a U.S. subsidiary of Serono International, S.A., organized under the laws of Massachusetts and both located and headquartered at One Technology Place, Rockland, Massachusetts, 02370.

33. At all times material hereto, Serono acted by and through its duly authorized agents, employees, and representatives who were acting within the course and scope of their agency, employment and representation, all of whom were acting at the direction of or with the consent, permission and authorization of Serono.

34. At all times material hereto, whenever this class action complaint refers to any acts of Serono, the reference shall be deemed to mean that of the directors, officers, employees, or agents of Serono authorized such acts while actively engaging in the management, direction, or control of the affairs of Serono, and while acting within the scope of their agency or employment.

35. RJL Systems, Inc., later known as RJL Sciences, Inc., is a corporation located in Clinton Township, Michigan, in the business of developing and marketing bioelectrical resistance and reactance measurement devices and associated computer software.

36. Rudolph J. Liedtke was the president and principal owner of RJL Systems, Inc.

III. JURISDICTION

37. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, and pursuant to 28 U.S.C. § 1964(c), because this action alleges violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

38. Plaintiffs also invoke jurisdiction pursuant to 28 U.S.C. § 1332 (d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interests and costs, and is a class action in which "any member of a class of plaintiffs is a citizen of a state different from any defendant."

39. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 (b) and (c), and 18 U.S.C. § 1965(a), because one or more defendants transact business, are found, or have agents in this District, and because a substantial portion of part or all of the alleged improper conduct took place in this District. Serono, through its maintenance of its principal place of business for its U.S. operations in this District and Serono, RJL and Liedtke, through their marketing and sales of Serostim and related medical devices and software, have transacted substantial business in this District.

IV. FACTS

A. Introduction of Serostim

40. Serono marketed and sold the drug Serostim, which is the proprietary name or trademark of the generic drug, "somatropin." Somatropin is recombinant human growth hormone, consisting generally of growth hormone taken from a mammalian cell line and modified, using recombinant DNA technology, by adding the human growth hormone gene.

41. Serono received accelerated approval from the FDA in August of 1996 for Serostim to treat AIDS wasting, also know as cachexia, a condition involving profound involuntary weight loss in AIDS patients, with a preferential loss of lean body mass over fat mass. At the time that the FDA approved Serostim, AIDS wasting was an AIDS defining condition that constituted the leading cause of death among AIDS patients.

42. Serostim was an injectable drug that was prescribed on a per milligram basis and was dispensed in vials. The dose most commonly administered was 6mg per day. In August 1996, the FDA approved Serostim based upon a 12-week course of treatment, although many patients received Serostim for more than 12 weeks.

43. Serostim was a very expensive drug. Serono set the average wholesale price ("AWP") for Serostim at $42 per mg. At 6mg per day, a 12-week course of Serostim therapy cost approximately $21,168.

44. Serostim came on the market concurrently with the advent of protease inhibitor drugs. These drugs, often referred to as Highly Active Anti-Retroviral Therapy, or HAART, dramatically curtailed, in the United States, the proliferation of the AIDS virus itself, particularly when used in combination with one another (commonly referred to as the "AIDS cocktail"). Given the decreased viral loads in HIV-positive patients taking these drugs, the

incidence and prevalence of the AIDS wasting syndrome began to markedly decline among AIDS patients. Consequently, the medical necessity for Serostim began to diminish following the drug's launch. Serono knew or had reason to believe that decline in commercial demand for the drug would follow.

B. Serono's Campaign to Redefine AIDS Wasting

45. Commencing in 1997, and continuing thereafter, in order to salvage what it had expected to be a highly profitable market, Serono launched a campaign to "redefine AIDS wasting." Serono's goal was to create a market for Serostim by expanding the disease state for which Serostim could be prescribed as a treatment. Serono trained its sales force to make sales presentations and disseminate literature stating wasting was being "masked" by weight gain in the post-HAART era and that patients were still experiencing AIDS wasting following the advent of HAART, despite an absence of weight loss.

46. Serono also trained its sales and marketing employees to represent to physicians, patients, and others that "body cell mass" ("BCM") was the most metabolically active component of the body and that patients who had lost BCM were wasting, even if they had lost no weight or had actually gained weight. Serono represented that estimates of body cell mass in humans could be made by using bioelectrical impedance analysis ("BIA") medical devices in conjunction with certain software devices that purported to compute estimates of body cell mass. To "unmask" AIDS wasting, Serono, in concert with RJL, promoted the use of the BIA and accompanying computer software devices to measure body cell mass.

47. During the clinical trials performed to obtain FDA approval for Serostim, the safety, efficacy, and necessity of Serostim were evaluated in test subjects who were diagnosed as suffering from AIDS wasting based upon changes in the amount of weight and

lean body mass the subjects had experienced. Neither BCM testing nor BIA devices and associated software were ever used as a diagnostic tool to identify AIDS patients for whom Serostim therapy would be safe, effective, or necessary.

48. The BIA and software devices Serono used to promote sales of Serostim were developed and marketed by RJL Systems, Inc., later known as RJL Sciences, Inc. (hereinafter "RJL"), and Rudolph J. Liedtke (hereinafter "Liedtke"), the President and principal owner of RJL. These medical devices and software were never scientifically tested in conjunction with the diagnosis of AIDS wasting.

49. The BIA devices sold by RJL and Liedtke consisted of a portable device with two protruding electrodes to be attached to the hand and foot of human test subjects. Defendants represented that the BIA devices purported to measure the rate at which low levels of electrical current would pass through the body. A microchip embedded in the BIA device measured the degree to which the electrical current encountered "impedance" while passing through the body and calculated "resistance" and "reactance" measurements. The resistance and reactance measurements obtained by performing a BIA test reflected the degree to which the subject's body resisted the flow of the current and the extent to which the current was stored in the body.

50. Defendants represented that the resistance and reactance measurements generated by the BIA device were used to estimate the body composition of individual humans. Estimate of body composition were computed by applying the resistance and reactance measurements generated by the BIA device to predicative equations.

51. Defendants represented that predicative equations were developed by mathematically calculating the statistical relationship between the resistance and reactance

measurements obtained and by performing BIA tests on a sample populations of human subjects and actual measurements of body compositions of humans varied depending on the characteristics and size of the sample population used to develop the equation and on the methodology used to measure the body composition within that population.

52. Defendant Serono purchased and distributed, and caused to be purchased and distributed by others, the BIA medical devices and associated software developed and marketed by RJL and Liedtke. Serono also promoted the BIA medical devices and associated software for the purpose – unapproved by the FDA and scientifically unproven – of identifying AIDS victims whose purported non-weight losing AIDS wasting symptoms should be treated with Serostim.

C. The Regulatory Framework for Approval of Medical Devices

53. The BIA device was a medical device within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321(h), in that the BIA device was an impendence plethysmograph used to estimate human body composition by estimating "peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs" 21 C.F.R. § 870.2770.

54. Each package of computer software used to convert the resistance and reactance measurements generated by the BIA device into estimates of body composition was also a medical device within the meaning of the FDCA in that it was a "component, part, or accessory" to BIA devices pursuant to 21 U.S.C. § 321(h).

55. The Center for Devices and Radiological Health ("CDRH") was the office within the FDA responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law.

56. The BIA and computer software devices could not be sold without first obtaining premarket clearance and premarket approval from the FDA, depending on the intended use of the devices. FDA could grant a 510(k) premarket clearance if it determined, following review of the data submitted in support of the applicant's premarket notification, that a device was substantially equivalent to a device (known as a "predicate device") that was marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Food, Drug and Cosmetics Act ("FDCA").

57. A device could only be found substantially equivalent to a predicate device if, among other things, the intended use of the current device was the same as the intended use of a predicate device. If the intended use of the device was different from the intended use of a predicate device, substantial equivalence could not be found. Under such circumstances, it was illegal for a manufacturer to market the device in interstate commerce unless the FDA had first reviewed and approved a premarket application to market the device.

58. FDA categorized devices into three classes – Class I, Class II, and Class III -- depending on the degree of regulation necessary to ensure the safety and effectiveness of the devices for their intended uses. Devices that were first introduced into commercial distribution after May 28, 1976, were presumed to be Class III devices by operation of law. 21 U.S.C. § 360c(f)(1). A Class III device, unless the subject of a 510(k) premarket clearance, required premarket approval before it could be legally marketed in interstate commerce. 21 U.S.C. § 360e. Premarket approval review by the FDA generally entailed, among other things, a review of clinical trials and scientific data offered to confirm the safety and efficacy of the device as well as a review of the device's labeling, which must include adequate directions for use.

59. On or about June 24, 1986, RJL and Liedtke submitted a 510(k) premarket notification to FDA's CDRH relating to a BIA device identified therein as "Body Comp Analyzer" and a computer software device accompanying the device. In that 510(k) submission and in ensuing correspondence with CDRH, RJL and Liedtke stated that the Body Comp Analyzer and accompanying computer software had the same intended uses as those identified in a 510(k) premarket notification that RJL had filed with CDRH in 1983 – specifically, estimating total body water, lean body mass, and fat – and that the computer software only performed calculations that previously would have been done by hand to estimate body composition. RJL and Liedtke further represented that the predictive equations in the computer software were based on a population consisting of 278 healthy and obese college students whose body composition was measured through hydrostatic weighing. RJL and Liedtke also stated that total body water measurements of the college students were determined using deuterium oxide dilution. RJL and Liedtke represented to CDRH that the intended uses of the BIA device and accompanying computer software did not include measuring body cell mass or diagnosing any disease state.

60. Based on the representations made by RJL and Liedtke in their 510(k) submission and related communications, CDRH concluded that the modified Body Comp Analyzer and accompanying software were substantially equivalent to a device marketed prior to the medical device amendments of 1976. On February 3, 1987, CDRH granted premarket clearance to RJL to distribute the Body Comp Analyzer and the accompanying computer software devices, referred to by CDRH as the "Modified Model BIA-103 Body Comp Analyzer," for the intended uses of estimating total body water, lean body mass, and fat in healthy humans.

D. The Unapproved Development of Software Devices for Measuring Body Cell Mass

61. Serono, RJL, Liedtke, and others known and unknown developed various versions of software for the BIA medical device purported to calculate, among other things, body cell mass, total body water, fat free mass, and intracellular and extracellular water. The various software packages were named "Fluid and Nutrition Analysis," "Cyprus," "SomaScan," and "Cyprus 1.2 Condensed." Each of these software packages, pursuant to 21 U.S.C. § 351(f)(1)(B)(i), required FDA approval before they could be legally marketed for new and intended use of measuring body cell mass and/or diagnosing AIDS wasting based upon BIA resistance and reactance measurements. At no time did any individual or entity submit an application for premarket approval to the FDA with respect to any of these software packages, nor has FDA ever approved an application for premarket approval for any of the software packages under 21 U.S.C. § 360e.

1. The FNA Software

62. Commencing in at least 1994, RJL and Liedtke and others unknown developed a predicative equation that would purportedly calculate estimates of body cell mass using the BIA resistance and reactance readings. This predicative equation (herein after the "Z equation") purported to estimate body cell mass based upon measurements of total body potassium in a population referred to herein as the "ABC database" that consisted of approximately 332 humans, including individuals who were healthy and others who had been tested as HIV-positive.

63. Commencing sometime during 1994, RJL and Liedtke, and others unknown, developed new computer software for use in interpreting BIA test results as a tool for diagnosing AIDS wasting. The software incorporated the Z equation. RJL and Liedtke marketed the software under the name "Fluid and Nutrition Analysis," ("FNA"). The FNA

software purported to calculate an individual's estimated body cell mass, total body water, intracellular and extracellular water, fat free mass, extracellular tissue, and fat. The FNA software also computed purported "normal" ranges for the individual's total body water and intracellular and extracellular water by comparing the individual's BIA test results to that of a select portion of the population included in the purported ABC database. The inclusion of the Z equation and the database in the FNA software, and the use of the computer software to purportedly measure body cell mass and as a tool for diagnosing AIDS wasting, were new intended uses that required premarket approval from FDA before their introduction into interstate commerce as a basis for diagnosing AIDS wasting and promotion of the administration of Serostim as treatment.

64. In or about January, 1995, RJL and Liedtke met with representatives of Serono and with others unknown concerning the use of BIA technology by Serono in the promotion of Serostim.

65. Between September 1995 and June 1996, RJL shipped approximately 25 BIA devices together with FNA Version 3.1 software packages to Serono for use by Serono in evaluating body composition in AIDS patients.

2. The Cyprus Software

66. The "Cyprus" software, developed for the BIA medical device commencing in or about 1998, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The Cyprus software further computed purported normal ranges for each of these measurements for individuals by comparing the individual's test results to a select portion of database of humans derived from the National Health and Nutrition Examination Survey (NHANES).

3. The SomaScan Software

67. The "SomaScan" software, developed for the BIA device commencing in or about August, 1999, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The SomaScan software further computed purported precise "ideal" amounts for each of these measurements for individual test subjects by comparing the individual's test results to a select portion of the NHANES database and eliminating any standard deviation from the calculations. The SomaScan software was not submitted to FDA for premarket approval and was not approved by FDA for shipment in interstate commerce for the intended uses of measuring body cell mass or diagnosing AIDS wasting. The inclusion of the Z equation, employing the NHANES database as the population base for computing "ideal" body composition values in the SomaScan software, and the use of the computer software to measure body cell mass and as a tool for diagnosing AIDS wasting, were new intended uses, and required premarket approval from FDA before their introduction into interstate commerce and use as a basis for diagnosis of AIDS wasting and promotion of the administration of Serostim as treatment.

4. The Cyprus 1.2 Condensed Software

68. The "Cyprus 1.2 Condensed" software, developed for the BIA device in or about February, 2000, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The Cyprus 1.2 Condensed software also computed purported "normal" amounts and "normal" ranges for these values for each individual by comparing the individual test subject's results to a select portion of the NHANES database and including a standard deviation for these calculations. The inclusion of

the Z equation, employing the NHANES database as the population base for computing "normal" body composition values in the software, and the use of the computer software to measure body cell mass and as a tool for diagnosing AIDS wasting, were new intended uses, and required premarket approval from FDA before introduction into interstate commerce and use in the diagnosis of AIDS wasting and the promotion of administration of Serostim as treatment.

E. Defendants' Fraudulent Promotion of Serostim Through Use of the Unapproved and Unproven Medical Devices and Associated Software

69. Commencing as early as September, 1996, and continuing thereafter, Serono, RJL, Liedtke, and others unknown, knowingly and willfully agreed to introduce and deliver for introduction into interstate commerce, with intent to defraud and mislead, BIA computer software for use in diagnosing AIDS wasting based upon BIA resistance and reactance measurements, knowing that these devices had not been approved for use diagnosing AIDS wasting and were therefore adulterated medical devices within the meaning of 21 U.S.C. § 351(f)(1)(B)(i). In engaging in this conduct, Serono, RJL, Liedtke, and others unknown formed the Medical Device Enterprise.

70. The purpose of the Medical Device Enterprise was to introduce and deliver into interstate commerce with intent to defraud and mislead unapproved, adulterated and unproven medical devices in order to create a basis for the promotion and sale of Serostim prescriptions where no medical necessity for the drug existed. The purpose of the Medical Device Enterprise was also to increase the market and sales of BIA devices and software.

71. Serono, RJL, Liedtke, and others unknown, did in fact participate in the development and dissemination of BIA computer software that purported to measure body cell mass for use in diagnosing AIDS wasting based upon a test subject's purported loss of body

cell mass. The disease state of AIDS wasting, however, consisted of profound involuntary weight loss and loss of lean body mass in AIDS patients, not loss of body cell mass. Use of BIA devices and computer software that purported to measure loss of body cell mass enabled Serono and others unknown, including RJL and Liedtke, to "redefine" AIDS wasting market for Serostim beyond the disease state for which the drug was approved and scientifically proven to be necessary, and caused consumers and third-party payors to pay for Serostim therapy that was medically unnecessary and potentially unsafe. It also provided a stimulus for increased sales of the BIA devices and associated software.

72. As part of the Medical Device Enterprise, Serono also disseminated BIA devices and related software in interstate commerce to its sales representatives to promote sales of Serostim based on purported loss of body cell mass, even without evidence of weight loss. This was done without first obtaining FDA approval for this use of the device with the FNA software, or without proving its validity.

73. Serono, RJL, and Liedtke also developed and disseminated the "SomaScan" software in interstate commerce to sales representatives of Serono and to others unknown in order to promote the diagnosis of AIDS wasting as a disease state involving the loss of body cell mass and to compute purported "ideal" levels of body cell mass and other body composition parameters for individual BIA test subjects, all without first obtaining FDA approval for these uses of the device with the SomaScan software or proving its medical effectiveness or necessity. In doing so, Defendants and the Medical Device Enterprise sought to create a purported basis for the prescribing and sale of Serostim for medically unnecessary purposes and increase the prescribing and sale of Serostim.

74. Serono, RJL, and Liedtke also developed and disseminated the "Cyprus 1.2 Condensed" software in interstate commerce to sales representatives of Serono and to others unknown in order to promote the diagnosis of AIDS wasting as a disease state involving the loss of body cell mass and to compute purported "normal" levels of body cell mass and other body composition parameters, all without first obtaining FDA approval for these uses of the device with the Cyprus 1.2 Condensed software or proving its medical effectiveness or necessity. In so doing, Defendants and the Medical Device Enterprise sought to increase the market potential for Serostim and to create a purported basis for prescribing and sale of Serostim for medically unnecessary purposes.

75. Serono, RJL, and Liedtke also sought to provide a basis for Serono and others unknown to induce physicians to prescribe, and third-party payors to pay for, Serostim based upon misrepresentations and omissions of material facts. Serono misled physicians and third-party payors regarding the validity of BIA testing in diagnosing AIDS wasting and did not disclose that BIA software devices had not been approved by FDA or scientifically validated for the purposes of determining whether patients were experiencing purported changes in body cell mass or suffering from AIDS wasting.

76. As a consequence of these material misrepresentations and omissions, Defendants individually and through the Medical Device Enterprise caused consumers and third-party payors to reimburse for Serostim prescriptions that would not have been written and for which the third-party payors would decline to have paid.

F. Defendants' Agreements and Actions to Implement Use of the Unapproved and Unproven Medical Devices to Support Fraudulent Bases for Serostim Prescriptions

77. Beginning in 1996, Serono, RJL, Liedtke, and others unknown, embarked on a campaign to improperly promote and market BIA and associated computer software in